5. 510(K) SUMMARY

APR - 8 2008

DATE: March 10, 2008

OWNER:
Baxter Healthcare Corporation
One Deerfield Parkway
Deerfield, IL 60015

CONTACT PERSON:
Barbara Barbeau
Senior Director, Global Regulatory Affairs
1620 Waukegan Road, MPGR-AL
McGaw Park, IL 60085
Telephone: 847-473-6274
Fax: 847-785-5116
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DEVICE NAME:
Proprietary Name: TricOs T[1] Resorbable Bone Substitute
Common/Usual Name: Bone Void Filler
Classification Name: Resorbable Calcium Salt Bone Void Filler
Product Code: LYC

PREDICATE DEVICES:
TricOs T Resorbable Bone Substitute (K051722)

Geistlich BIO-OSS®, BIO-OSS® Blocks and BIO-OSS® Collagen (K033815)

STATEMENT OF INTENDED USE:
TricOs T Resorbable Bone Substitute is indicated for use as a bone void filler for voids and gaps that are not intrinsic to the stability of the bony structure. It is indicated for surgically created osseous defects or osseous defects resulting from traumatic injury. TricOs T Resorbable Bone Substitute is intended to fill, augment, or reconstruct bony defects of the oral and maxillofacial region. Following placement in bony voids or gaps, TricOs T Resorbable Bone Substitute is

[1] TricOs T is a trademark of Baxter Healthcare Corporation

resorbed while providing support for the in-growth of bone during the healing process. TricOs T Resorbable Bone Substitute is a bone void filler without initial mechanical properties, therefore rigid fixation techniques are recommended.

DEVICE DESCRIPTION:

TricOs T Resorbable Bone Substitute consists of an inorganic calcium phosphate scaffold that is mixed with a heterologous human fibrin matrix prior to application. The fibrin matrix acts as a binder for the calcium phosphate scaffold, imparting favorable handling characteristics to the product to facilitate the surgical procedure, and acting as a three-dimensional matrix that supports the in-growth of bone.

TECHNOLOGICAL CHARACTERISTICS:

TricOs T Resorbable Bone Substitute for oral and maxillofacial region is substantially equivalent to Baxter's current legally marketed TricOs T Resorbable Bone Substitute cleared by 510(k) K051722 with regard to technological characteristics, performance, and components. The Baxter TricOs T Resorbable Bone Substitute is intended for oral and maxillofacial applications in the same capacity as the BIO-OSS®, BIO-OSS® Blocks and BIO-OSS® Collagen products (K033815).

ASSESSMENT OF NONCLINICAL DATA:

The intended use of the subject device is being expanded to include bone void filling for the oral and maxillofacial region of the skeleton. The subject and predicate TricOs T device materials and component specifications are similar. The device components continue to meet the same material testing standards, and sterilization processing standards. Device performance as a bone void filler in the oral and maxillofacial region of the skeleton has been addressed by comparative testing in a sinus lift animal model

study. The results obtained from this study support the claim for substantial equivalence to BIO-OSS® devices for the new intended use.

CONCLUSIONS:

The proposed TricOs T Resorbable Bone Substitute has been verified against established standards and guidelines for its intended use. Testing demonstrates that the proposed device is as safe and effective as the predicate devices and the TricOs T Resorbable Bone Substitute performs well in skeletal and oral and maxillofacial region.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Barbara K. Barbeau
Sr. Director, Global Regulatory Affairs
Baxter Healthcare Corporation
1620 Waukegan Road MP GR-AL
McGaw Park, IL 60085

APR - 8 2008

Re: K073571
Trade/Device Name: TricOs T™ Resorbable Bone Substitute
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Codes: LYC and NUN
Dated: March 31, 2008
Received: April 1, 2008

Dear Ms. Barbeau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): **K073571**

Device Name: **TricOs T[1] Resorbable Bone Substitute**

Indication(s) for Use:

TricOs T Resorbable Bone Substitute is indicated for use as a bone void filler for voids and gaps that are not intrinsic to the stability of the bony structure. It is indicated for surgically created osseous defects or osseous defects resulting from traumatic injury. TricOs T Resorbable Bone Substitute is intended to fill, augment, or reconstruct bony defects of the oral and maxillofacial region. Following placement in bony voids or gaps, TricOs T Resorbable Bone Substitute is resorbed while providing support for the in-growth of bone during the healing process. TricOs T Resorbable Bone Substitute is a bone void filler without initial mechanical properties, therefore rigid fixation techniques are recommended.

Prescription Use: ☑	Over-the-Counter Use: ☐
21 CFR 801 Subpart D	21 CFR Subpart C

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073571

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